UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION)))) MDL No. 2419
THIS DOCUMENT RELATES TO:) Dkt. No 1:13-md-2419 (RWZ)
Suits Naming the Tennessee Clinic Defendants)))

TENNESSEE CLINIC DEFENDANTS' BRIEF SETTING FORTH POSITION REGARDING BELLWETHER SELECTION

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively the "Tennessee Clinic Defendants") hereby file this brief setting forth their position on how the first bellwether trial cases should be selected. The Tennessee Clinic Defendants file this brief consistent with MDL Order No. 9¹ and the Court's instructions at the April 29, 2015 status conference².

¹ Dkt. 1425

² Hr'g Tr. 7:8-19 (April 29, 2015 status conference).

Background

The vast majority of cases against the Tennessee Clinic Defendants were transferred to the MDL beginning in the fall of 2013. There are currently 117 Plaintiffs with suits pending against the STOPNC Defendants,³ 24 Plaintiffs with suits pending against the SSC Defendants,⁴ and two (2) Plaintiffs with suits pending against Donald E. Jones, MD⁵.⁶ Since the cases against the Tennessee Clinic Defendants entered the MDL, the litigation has steadily unfolded, with numerous moving parts. Relevant dates leading up to this brief include:

<u>September 16, 2013</u>: With the cases against the Tennessee Clinic Defendants barely in the embryonic stage, the PSC filed a motion requesting that the Court enter an order with deadlines for selecting bellwether trials.⁷

<u>January 31, 2014</u>: Less than 90 days after filing the Master Complaint, the PSC again filed a motion requesting that the Court enter an order that included deadlines for selecting bellwether cases.⁸

<u>September 18, 2014</u>: The Court entered an order setting a schedule for "common" discovery, which included a deadline for submitting a proposed procedure for selecting bellwethers.⁹ 10

March 6, 2015: The PSC completely reversed course and asked the Court to abandon the bellwether process in favor of a consolidated, expedited trial of six cases unilaterally chosen by the PSC, to be tried in December 2015.¹¹ 12

⁸ At this point, again, the MDL was just taking shape. The Court did not even rule on the threshold legal issues in the collective defendants' motions to dismiss until August 29, 2014. Dkt. 1360.

⁹ Dkt. 1425.

³ Saint Thomas Outpatient Neurosurgical Center ("STOPNC"), Howell Allen Clinic, John Culclasure, MD, and Debra Schamberg, RN, CNOR.

⁴ Specialty Surgery Center ("SSC"), Kenneth Lister, MD, and Kenneth Lister, MD, PC.

⁵ The Tennessee Clinic Defendants understand that the PSC intends to move for a stay of the two cases against Dr. Jones, which the Tennessee Clinic Defendants do not oppose, while the cases against the STOPNC Defendants are pushed to the forefront for the first bellwether trials.

⁶ This is the number of patients who have sued the Tennessee Clinic Defendants. These numbers do not include consortium-Plaintiffs.

⁷ Dkt. 431.

¹⁰ At this point, with the initial discovery order entered, the MDL against the Tennessee Clinic Defendants moved squarely into "litigation mode."

¹¹ Dkts. 1716, 1717.

¹² Of note, the PSC asked the Court to set a trial date at a point when only a handful of the dozens of fact depositions in the "common" discovery phase had occurred; no expert discovery had occurred; no

April 29, 2015: At the monthly status conference, the Court ordered the parties to stay the course and submit their bellwether proposals in accordance with MDL Order No. 9.¹³

May 11, 2015: The PSC sent a bellwether proposal to the Tennessee Clinic Defendants for discussion. The parties held a conference call on May 12 to discuss it. The Tennessee Clinic Defendants (along with the Saint Thomas Entities) revised the PSC's draft proposal and sent the revised version to the PSC on May 16. The parties were able to reach agreement on several issues and will continue to try to work on other issues before the hearings on May 28.

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The parties, conceptually, appear to now have somewhat similar views on a bellwether *process*.¹⁴ There are some disagreements about certain *aspects* of the process for selecting the cases. But, overall, all Tennessee parties (including, now it appears, the PSC) seem to agree that a step-by-step process should be put in place to select a subset of trial cases, and that those cases should lead the trial process.

One primary, fundamental disagreement between the sides is the *timing* of the implementation of the process and the first trials. The PSC ignores the amount of discovery left to be done and pushes for trials to occur in late-2015, on an impossible pace. The Tennessee Clinic Defendants share an interest in an efficient move toward trial. Unfortunately, the PSC's proposed timeline is unattainable. The parties briefed the disagreement on *timing* at Dkts. 1716 (PSC's motion), 1753/1754 (responses by Tennessee Healthcare Defendants), and 1771 (PSC's reply). The instant brief will not

bellwether plan had been put in place; no plan for case-specific discovery had been put in place; and no case-specific discovery had occurred or was scheduled.

¹³ Hr'g Tr. 7:8-19 (April 29, 2015 status conference).

¹⁴ The PSC, in its March 6, 2015, motion, appeared to favor abandoning the bellwether process for an expedited six-plaintiff consolidated trial. On May 11, 2015, the PSC circulated a proposed order setting forth a bellwether process, which seems to indicate a return to the PSC's original position. So, the PSC appears back on board with some sort of bellwether process to select single-plaintiff cases.

again address, at length, the *timing* issues. The instant brief instead explains the Tennessee Clinic Defendants' proposed *process* to select representative cases.¹⁵

Law and Argument

I. The Court should adopt a bellwether selection process for choosing the first cases for trial.

Prior to the PSC's abrupt change of position on bellwether trials in March 2015, the parties agreed that these 100+ cases should proceed to trial using a process for selecting a subset of representative cases (bellwether cases) to be tried first. The value of using bellwether trials has been briefed extensively. These Defendants will not cover ground already covered in detail, except to highlight three points:

- 1. Bellwether trials are becoming standard practice in MDL proceedings. 17
- 2. The Honorable Eldon E. Fallon, considered by many to be an authority on management of mass tort litigation, advocates for the use of bellwether trials in MDL proceedings.¹⁸
- 3. The Manual for Complex Litigation (4th Ed.) advocates for bellwether trials to resolve mass tort cases.¹⁹

To the extent there is any dispute, the Tennessee Clinic Defendants wholeheartedly believe that the Court should adopt a procedure for selecting a subset of representative, bellwether cases to be tried first.

¹⁷ In Re: Propulsid Products Liability Litigation, MDL 1355; In Re: Vioxx Products Liability Litigation, MDL 1657; In Re: Fresenius Granuflo/Naturalyte Dialysate Products Liability Litigation, MDL 2428; Chinese-Manufactured Drywall Products Liability Litigation, MDL 2047.

¹⁵ The Tennessee Clinic Defendants' proposed order on bellwether selection is attached as Exhibit 1.

¹⁶ See. e.a., Dkt. 457, 1754.

¹⁸ Fallon, et al., Bellwether Trials in Multidistrict Litigation, 82 TULANE LAW REV. 2323 (2008) (hereinafter Fallon).

¹⁹ Manual for Complex Litigation, Fourth, 225, 360.

II. The bellwether selection process should be clinic-specific.

To the extent there is any dispute, the current status of this litigation virtually requires a *clinic*-specific bellwether trial process as opposed to a national selection process.

All of the Affiliated and National Defendants have now (pending approval by the bankruptcy court) settled the claims against them. This shifts the focus in the short-term to the state-specific defendants, removing any benefit to a national bellwether pool and requiring the Court to institute a state-by-state approach.²⁰

Even more specifically, the factual allegations of the lawsuits are *clinic*-specific such that a result in a case against one clinic offers little predictive value for a case against another clinic.²¹ The predominant allegation in these cases is that the clinics negligently purchased from NECC. However, the motivation for the purchase decision and the due diligence conducted prior to purchasing varies from clinic-to-clinic.²² This makes a national bellwether process yield little value. It must be done clinic-by-clinic.

Relatedly, varying statutes of limitations have resulted in litigation proceeding at different paces for each clinic, meaning that many cases simply will not be "trial ready" at the same time.²³ As a result, a national bellwether process is practically unworkable.

²⁰ For example, assume the Court were to institute a bellwether process that includes an initial set of trial cases from different states. A collection of 4-5 verdicts against a "mixed bag" of state defendants (e.g., a defense verdict in a Michigan case, a small plaintiff's verdict in a Tennessee case, a large plaintiff's verdict in an Indiana case, and a hung jury in a New Jersey case) would not offer sufficient state-specific data to be statistically significant and facilitate settlement.

So, the parties should choose from the universe of cases against the each clinic.

Additionally, variations in state law make comparison of trial outcomes between clinics virtually

impossible. For example, Tennessee has caps on noneconomic damages.

23 E.g., the Tennessee Clinic Defendants' primary witnesses have already been deposed while Box Hill Surgery Center, a Maryland clinic, was just served with written discovery. Dkts. 1803, 1835.

Thus, the Tennessee Clinic Defendants respectfully request that the Court adopt a clinic-specific bellwether selection process in which four (4) cases against the STOPNC Defendants will be selected and prepared for trial.²⁴

III. The bellwether selection process should result in the selection of representative cases from the five major categories of injury.

The purpose of bellwether trials is to conduct representative trials in order to give parties information that they can then use to predict the outcome of the remaining cases in order to facilitate a global resolution.²⁵

"If individual trials, sometimes referred to as bellwether trials or test cases, are to produce reliable information about other mass tort cases, the specific plaintiffs and their claims should be representative of the range of cases."26 Without representative bellwethers, "the transferee court and the attorneys risk trying an anomalous case, thereby wasting substantial time and money."²⁷

There are many procedures that can be employed for selecting representative cases. The most obvious methods are (1) the parties choose the cases; (2) the court chooses the cases; or (3) some combination of (1) and (2). No solution is perfect. The problem with giving the parties control over selection of the cases is that there is a natural tendency for the parties to select cases that are the best for them, rather than representative cases.²⁸ The problem with having the court choose the cases is that it

²⁷ Fallon, 2344.

²⁴ The Tennessee Clinic Defendants recognize that the initial proposals focus on the STOPNC Defendants, but the Tennessee Clinic Defendants expect to propose a similar process for three (3) cases against the SSC Defendants to be selected and prepared for trial. Fallon, 2343.

²⁶ Manual for Complex Litigation, Fourth, 360.

²⁸ This is the major problem with the PSC's proposed methodology. The Court need only look at the first six cases proposed by the PSC to see the moral hazard of self-selection in action. Dkts. 1716, 1717. The PSC proposed trying cases with damages numbers way out-of-line with the median cases. In their

imposes a substantial burden on the court to familiarize itself with all of the cases in order to make an informed decision. A hybrid is the best choice.

The Tennessee Clinic Defendants propose the following general framework for choosing cases:

- 1. The Court will provide guidance to the parties as to (1) the categories from which they must pick the candidate cases and (2) the factors that should be considered when the parties propose potential bellwether trial cases.
- 2. The parties then, considering the factors outlined by the Court, select 16 total cases (eight cases selected by each side). This creates a pool of 16 candidate bellwether trial cases.
- 3. Each side may strike four of the other side's eight cases. This leaves a pool of eight candidate bellwether trial cases.
- 4. From the eight remaining bellwether trial candidates, the Court will choose four representative cases for trial based on briefs submitted by the parties.²⁹

Both (1) intervention by the Court at the beginning (mandating selection from certain injury categories and delineating the factors the parties should consider in making their proposals) and end of the selection process (selecting the cases for actual trial) and (2) the ability of the parties to strike some of the other side's cases *should* counteract the parties' natural inclination to select the cases that are best for them and increase the likelihood that true representative bellwethers are selected for trial.

The Tennessee Clinic Defendants' proposed selection procedure is discussed in more detail below.

response to the PSC's motion for an expedited trial, the Tennessee Clinic Defendants discussed, at length, the PSC's failure to select representative cases. Dkt. 1754.

Attached as Exhibit 2 is a flow chart demonstrating, conceptually, how the Tennessee Clinic Defendants' bellwether proposal would operate.

a. The Court should direct each side should to choose cases from every major injury category.

The Court should begin with a direction that the parties select a case from each major injury category. Doing so will create a pool of candidates that best reflects the makeup of the entire universe of cases.

To assist in selecting representative cases, Judge Fallon recommends using a mechanism, such as plaintiff profile forms, to inventory the entire universe of cases and break them down into major categories.³⁰ Here, the Plaintiffs in the suits against the STOPNC Defendants have completed Plaintiff Profile Forms, allowing for categorization by type of injury.³¹ The Plaintiffs' injuries can be separated into five major injury categories:

- 1. Death
- 2. Fungal meningitis <u>and</u> localized fungal infection
- 3. Fungal meningitis only
- 4. Localized fungal infection only (not meningitis)
- 5. No disease.³²

The cases against the STOPNC Defendants break down as follows³³:

<u>Injury</u>	<u>Number</u>	Percentage of all cases
Death	14	12%
Fungal meningitis + localized fungal infection	45	38%
Fungal meningitis only	19	16%
Localized fungal infection only	13	11%
No disease	28	24%

³¹ The PSC, Trustee, and Creditors' Committee created the Claims Resolution Facility for the Tort Trust in NECC's bankruptcy to assist in valuing tort claims for payment from the bankruptcy settlement. It also uses type of injury as the primary factor for classifying cases. Dkt. 1694-3, pp. 8-15.

³⁰ Fallon, 2344.

³² "No disease" cases are those in which the Plaintiff was not diagnosed and treated for a fungal infection.
³³ The Tennessee Clinic Defendants have updated these numbers since they submitted their response to the PSC's motion for an expedited trial date which included a similar chart. The Defendants are still in the process of collecting, reviewing, and analyzing the Plaintiffs' medical records, which may (to some degree) affect these numbers.

In order to maximize predictive value, cases must be selected from each major injury category. For example, the damages awarded in a death case are of little use in predicting the damages in a "no disease" case. The parties need to be able to compare "apples to apples."

Accordingly, the Tennessee Clinic Defendants propose that, when each side selects its eight cases to populate the bellwether candidate pool of 16, each side must include at least one case (but no more than two) from each major injury category. This will ensure that the pool of potential cases is populated with a balanced mix of cases from all injury categories.³⁴

³⁴ For example, assume the *Plaintiffs* choose:

Category	Plaintiffs' Choices for Initial Pool:
Death	Two cases
Fungal meningitis and localized fungal infection	Two cases
Fungal meningitis only	Two cases
Localized fungal infection only (not meningitis)	One case
No disease	One case
Total:	Eight cases

Then, assume the Defendants choose:

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Category	Defendants' Choices for Initial Pool:	
Death	One case	
Fungal meningitis and localized fungal infection	One case	
Fungal meningitis only	Two cases	
Localized fungal infection only (not meningitis)	Two cases	
No disease	Two cases	
Total:	Eight cases	

This would provide an initial bellwether candidate pool of 16 cases with 3-4 cases from each major injury category, a pool that is fairly representative of the entire universe of cases.

b. The Court should order the parties to consider additional variables when selecting cases.

Next, the Court should direct the parties to consider additional litigation variables when selecting their eight proposed bellwether cases. Major injury category is not the only factor that should be considered when selecting candidates. For example, there is variation in the type and magnitude of damages sought by the Plaintiffs. Some Plaintiffs seek lost wages or bring loss of consortium claims. Some do not. Likewise, Plaintiffs in the same injury category may have very different courses of treatment. Some Plaintiffs had relatively short hospitalizations while others required long hospitalizations with surgical intervention.

To account for these additional variables, the Tennessee Clinic Defendants propose that the Court order the parties to consider the following additional factors when selecting their eight proposed bellwether candidates³⁵:

- 1. The Plaintiff's demographic information and underlying health (e.g., age, gender, preexisting conditions, including autoimmune disorders, etc.)
- 2. The type and magnitude of damages sought by the Plaintiff (e.g., whether the Plaintiff is claiming lost wages; whether the suit includes a claim for loss of consortium; the amount of medical expenses for which the Plaintiff is seeking compensation, etc.)
- 3. The factors used for "Upward Adjustments" in the Claims Resolution Facility for administering the Tort Trust in NECC's bankruptcy case (e.g., whether the Plaintiff underwent surgery; whether the Plaintiff experienced complications from antifungal treatment. etc.).³⁶

³⁵ Selecting a perfectly representative case is obviously aspirational. Even if the Court orders the parties to consider certain variables in proposing trial candidates, the lawyers could still only select the "best" cases from each injury category. However, by identifying additional factors for selection on the front-end, the Court has already identified guidelines by which it can then eliminate those outlier cases when deciding on the first trial cases. ³⁶ Dkt. 1694-3, pp. 15-36.

These additional factors guide the parties on information that they should consider when proposing candidate cases.³⁷

c. Each side should be permitted to strike four of the other side's eight cases.

Once the parties have populated the pool of 16 potential bellwethers from the defined injury categories and considering the additional specified factors, each side should be allowed to strike four of the other side's eight cases.³⁸ This reduces the pool to eight bellwether trial candidates.

This strike process serves two functions. First, it gives the parties the ability to strike cases that they believe are outliers or non-representative. Second, it reduces the number of cases that the Court must ultimately consider when selecting the final four cases for trial, resulting in less burden on the Court.

If the Defendants choose to settle one of the eight cases remaining after the strike process is complete, the Plaintiffs should be permitted to choose a replacement case from the same major injury category. On the other hand, if one of the remaining cases is dismissed (either voluntarily or by motion), the Defendants should be permitted to choose its replacement from the same major injury category.

³⁷ The Tennessee Clinic Defendants also recognize that not all cases fit neatly into each injury category, and not all factors can be used to identify the perfect bellwether case. Some flexibility will be needed, and reasonable discretion exercised, by the parties and Court.

³⁸ Fallon, 2365 ("Regardless of which method is ultimately employed, a transferee court should consider allowing each side of coordinating attorneys to veto or strike from consideration a predetermined number of cases in the trial-selection pool. No matter how diligently the attorneys or the transferee court fill the trial-selection pool, the possibility will always remain that, after the close of case-specific discovery, an unrepresentative case or a grossly unfavorable case will wind up in the trial-selection pool. By permitting the attorneys to strike or veto cases, the transferee court can minimize the chance that one of these outliers is selected as a bellwether trial, without having to disturb the preordained method of trial selection. In this way, if the abnormal case rears its head, the attorneys are equipped to deal with it on their own, without seeking court intervention.")

Additionally, the Plaintiffs should only be permitted to voluntarily dismiss any of the remaining eight cases <u>with prejudice</u>. This is a common occurrence in MDLs and rests well within the Court's discretion and authority under Fed. R. Civ. P. 41.³⁹ This provision prevents plaintiffs from commandeering the bellwether selection process by nonsuiting cases selected by the defendants until the defendants are left to choose from cases the plaintiffs prefer.

d. The parties should then submit position statements to the Court to assist the Court in selecting the first four cases for trial from the eight remaining proposed bellwether cases.

After the strike process is complete, eight potential bellwethers will remain in the pool. The Court should then choose the four cases that will proceed to case-specific discovery and trial.

Selection by the Court provides a final safeguard against outliers being selected for bellwether trials. The parties should be permitted to file limited briefs (ten pages or less) (1) proposing which four of the eight cases should be selected for trial and the proposed order and (2) explaining their bases for believing that those four cases should be tried first (*i.e.*, why they are representative). Once the Court selects the first four cases to be tried, the parties can proceed to case-specific discovery in those four cases on a *reasonable* schedule.

³⁹ See In re FEMA Trailer Formaldehyde Products Liability Litigation, 628 F.3d 157, 163 (5th Cir. 2010) (affirming dismissal with prejudice of suit selected as a bellwether noting, "[a]ny individual case may be selected as a bellwether, and no plaintiff has the right to avoid the obligation to proceed with his own suit, if so selected"); see also Dkt. 1717-1, Hr'g Tr. excerpt from Granuflo MDL attached to the PSC's Memorandum in Support of Motion for a Case Management Order Setting an Expedited Trial Date (noting the plaintiffs' voluntary dismissal with prejudice of multiple potential bellwethers selected by the defendants and discussing the most equitable way of replacing those cases).

IV. The schedule for selection and preparation of the initial cases chosen for trial should include reasonable, attainable deadlines.

The schedule set by the Court for completion of common discovery, bellwether selection, case-specific discovery, and pretrial motion practice must allow the parties to fully and fairly prepare these cases for trial. If the first trials are conducted on a rushed basis without full and fair discovery, the entire system fails.

In response to the PSC's motion for an expedited trial, the Tennessee Clinic Defendants discussed the multitude of reasons the PSC's proposed schedule is completely unworkable. 40 The PSC's proposal reflects no meaningful consideration of the amount of work that still needs to be done to prepare these cases for trial.⁴¹

Furthermore, the Tennessee Clinic Defendants agree with the Saint Thomas Entities that the common discovery deadline should be extended by 90 days and join in the Saint Thomas Entities' motion for a continuance.⁴²

The Tennessee Clinic Defendants propose the following schedule for selecting the four bellwether cases and preparing all four cases for trial by the end of 2016. When considering the case-specific discovery deadlines, it is important to keep in mind that the work required for each task will be quadrupled because the discovery will be conducted in four cases simultaneously.

⁴⁰ Dkt. 1754.

⁴¹ The PSC cannot dispute that there is a tremendous amount of work to completely prepare these cases for trial (including dozens of depositions), despite its motion for an expedited trial. Since the filing of the motion, the PSC has served multiple deposition notices and has demanded half of the deposition time for NECC, its Insiders, and Affiliates. See Dkts. 1839, 1800, 1786, 1783. Obviously, there is much work to be done, even by the PSC.

² Dkt. 1849. A formal motion for joinder from the Tennessee Clinic Defendants is forthcoming.

<u>Task</u>	<u>Deadline</u>
Each side will select eight cases as potential bellwethers, for a total of 16 cases	15 days from entry of order on bellwether selection procedure
Each side may strike four of the other side's eight cases	45 days from entry of order on bellwether selection procedure
Parties will file briefs of 10 pages or less proposing four cases for trial	75 days from entry of order on bellwether selection procedure
Parties will serve any case-specific written discovery in first four cases selected for trial	21 days from entry of order designating first four cases for trial
Parties will respond to case-specific written discovery in first four cases selected for trial	45 days from service of discovery
Parties will complete any case-specific fact depositions in first four cases selected for trial	90 days from entry of order designating first four cases for trial
Plaintiff will disclose case-specific experts in first four cases selected for trial	30 days from deadline for completion of case-specific depositions
Defendants will disclose case-specific experts in first four cases selected for trial	60 days from deadline for completion of case-specific depositions
Parties will complete depositions of case-specific experts in first four cases selected for trial	90 days from service of Defendants' expert reports ⁴³
Parties will file any case-specific Daubert or dispositive motions	60 days from completion of case- specific expert depositions
Parties will file any oppositions to case-specific <i>Daubert</i> or dispositive motions	30 days after the motion is filed
Parties will file replies in support of case-specific <i>Daubert</i> or dispositive motions	14 days after any oppositions are filed

Conclusion

For the foregoing reasons, the Tennessee Clinic Defendants respectfully request that the Court enter the proposed case management order governing bellwether selection attached hereto as Exhibit 1.

⁴³ The PSC's proposal provides that case-specific expert depositions may not begin until the Defendants' expert reports are served, and the Tennessee Clinic Defendants have agreed to this provision. But, the Defendants note that case-specific expert discovery could be completed sooner if the Plaintiffs will permit their experts to be deposed before the Defendants' expert reports are served.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 18th day of May, 2015.

/s/ Chris J. Tardio

Chris J. Tardio

^{*} Admitted pursuant to MDL Order No. 1.

^{**} Admitted pro hac vice.